

**Notice of Allowability**

Application No.

10/088,780

Applicant(s)

SECOMBES ET AL.

Examiner

Robert M. Kelly

Art Unit

1633

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/5/07.
2. ☒ The allowed claim(s) is/are 76-78.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application   |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>4/25/07</u> |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                                       |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                      |
|  | 9. <input type="checkbox"/> Other _____   |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kathleen Tyrrel on 4/25/07.

The application has been amended as follows:

#### IN THE CLAIMS:

1. Claim 76 has been amended as follows:

76. A ~~gene construct~~ plasmid for protection of a fish against viral haemorrhagic septicaemia virus (VHSV) comprising:

a non-infectious DNA nucleic acid construct encoding a viral haemorrhagic septicaemia virus-neutralizing single chain antibody BU1 comprising ~~Genebank Accession Number AF302092 with a DNA sequence~~

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cttaacegc ggagagctat aagttagata tcat (SEQ ID NO:1) encoding, operably linked to a secretion  
signal of transforming growth factor beta, linked to the 5' end of the single chain antibody BUI  
gene, said sequence being inserted into a plasmid downstream a CMV promoter, and upstream a  
polyadenylation signal.

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2. Claim 77 has been amended as follows:

77. A composition for passive immunization comprising the gene construct of claim 76 and a pharmaceutically acceptable diluent or carrier.

3. Claim 78 has been amended as follows:

78. A method for prophylactically treating fish against viral haemorrhagic septicaemia virus comprising administering the ~~composition~~plasmid of claim 776 to a fish via injection to the epaxial muscle below the dorsal fin of the fish.

IN THE ABSTRACT:

4. The abstract has been amended as follows:

The present invention relates to a non-infectious nucleic acid (RNA and DNA) construct constructed to express a recombinant antibody or antibody fragment in a host cell. The antibody molecule confers protection to the host against a pathogen, allergen or toxin. The host may be any animal including a human or a fish. More specifically, the antibody may be against viral haemorrhagic septicaemia virus.

The following is an examiner's statement of reasons for allowance:

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All of the previously pending claims have been cancelled, thereby mooted all rejections and/or objections to such claims, and therefore they are withdrawn. With regard to the newly presented claims, as amended by the Examiner, such claims overcome all the previous bases of rejection, being drawn to the construct and the treatment of fish in the method. As such, each composition claim is enabled for at least one embodiment, and the method claim is enabled for the full scope claimed. Still further, no prior art has been found to indicate that the specifically claimed sequence was known or obvious in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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